December 23, 2020

NeuroLogica Corporation, a subsidiary of Samsung Electronics
% Ninad Gujar, MBA, Ph.D.
Vice President, Regulatory Affairs and Quality Assurance
14 Electronics Avenue
DANVERS MA 01923

Re: K202526
Trade/Device Name: OmniTom Elite
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography -x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: December 4, 2020
Received: December 7, 2020

Dear Dr. Gujar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202526

Device Name
OmniTom Elite

Indications for Use *(Describe)*

The OmniTom Elite CT system is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 40cm field of view, primarily head and neck.

The CT system is intended to be used for both pediatric and adult imaging and as such has preset dose settings based upon weight and age. The CT images can be obtained either with or without contrast.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

In accordance with 21 CFR § 807.92, the 510(k) summary includes information on safety and effectiveness.

Date Prepared: August 28, 2020

Submitter
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Device

Trade Name:	OmniTom Elite
Device Model:	NL5000
Classification Name:	Computed Tomography X-ray System
Product Code:	JAK
Device Classification:	Class II (per 21 CFR § 892.1750)

Predicate Device

Trade Name:	OmniTom (K171183)
Classification Name:	Computed Tomography X-ray System
Product Code:	JAK
Device Classification:	Class II (per 21 CFR § 892.1750)

Device Description

The OmniTom Elite is an improved version of OmniTom computed tomography system, providing enhanced functionality. It still has the same high resolution, multi row, 40 cm bore, and 30 cm field of view x-ray computed tomography system. The lightweight translating gantry consists of a rotating disk with a solid state x-ray generator, Gd2O2S detector array, collimator, control computer, communications link, power slip-ring, data acquisition system, reconstruction computer, power system, brushless DC servo drive system (disk rotation) and an internal drive system (translation). The power system consists of batteries which provide system power while unplugged from the charging outlet. The system has the necessary safety features such as the emergency stop switch, x-ray indicators, interlocks, patient alignment laser and 110% x-ray timer. The gantry has omni-directional wheels that allow for robust diagonal, lateral, and rotational 360-degree movement and electrical drive system so the system can be moved easily to different locations.

Intended Use / Indications for Use

The OmniTom Elite CT system is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 40cm field of view, primarily head and neck.

The CT system is intended to be used for both pediatric and adult imaging and as such has preset dose settings based upon weight and age. The CT images can be obtained either with or without contrast.

Comparison of Technological Characteristics with the Predicate Device

We modified the cleared OmniTom (K171183) within our design controls to include technology improvements, that include hardware features like movement controls, power system efficiency, ruggedized covers and bumpers, patient auto alignment and software features like metal artifact reduction, CT angiography (CTA), CT perfusion (CTP), bolus tracking, axial and helical AEC and other post reconstruction enhancements. Both the predicate device (K171183) and the subject device have the same intended use.

OmniTom Elite, for its intended use, is of comparable type in design, material, functionality, and technology and is substantially equivalent to the cleared predicate device – OmniTom (K171183).

<u>Similarities</u>

- Design: The OmniTom Elite is similar in general design principle to OmniTom. and shares most of the control system designs and features of the OmniTom.

- Components: The OmniTom Elite uses similar components as the predicate device (OmniTom) such as x-ray generator, Gd2O2S detector array, collimator, slip ring, and data acquisition system.

Differences

The following differences exist between the subject device (OmniTom Elite) and the previously cleared predicate device (OmniTom K171183).

- Movement controls: The drive bar mechanism, system collision sensors, calibration were improved, in addition to audible and visual alerts for performance to avoid any possible unintentional or fast movement.

- Power system efficiency: Improved distribution of power in the system and design of the lithium batteries, allowing maintenance and protection of downstream electrical components. The design changes mitigate any inadvertent system shutdowns while providing health status on the operational state of the CT system and design changes increased mean time between failures (MTBF) for these critical components.

- Ruggedized covers and bumpers: Design changes were made for improved durability of the CT system.

- Patient auto alignment: Camera allows for rapid positioning of the scanner at the head of the bed, eliminating the need to adjust the patient bed.

- Metal artifact reduction (MAR): Streak artifacts are often seen around aneurysm clips, epilepsy probes or metal pins. The streaks can be reduced using MAR. Testing was carried out using an anatomical phantom and it was found that the MAR algorithm performs as indicated by successfully mitigating the streak artifacts that show up in the CT images without raising any new questions of safety or effectiveness of the device.

- CT angiography (CTA), CT perfusion (CTP), bolus tracking: OmniTom Elite has the ability for helical and dynamic scanning and includes dedicated functionality for contrast scanning. Similar to the predicate, OmniTom Elite does not control the dose, rate or route of administration for the contrast agent.

- Automatic exposure control (AEC): Both axial and helical AEC are included in OmniTom Elite for scanning with reduced radiation dose. AEC feature has been

verified as part of IEC 60601-2-44, clause 203.102 in OmniTom Elite similar to the predicate device.

- Post reconstruction enhancements: Reconstruction algorithms were enhanced for better image quality with the addition of specific features to allow modified slice spacing and thickness, reduced field of view.

- Mobile Stroke Unit: Rail and plate configuration is included in a kit for OmniTom Elite to be used in ambulance environment.

- Accessories: OmniTom Elite has various adapters to allow scanning with all compatible beds, a pediatric platform that will allow scanning from head to torso of up to a typical 7-year-old and radiolucent skull clamp kits for use during imaging in neurosurgical environment.

- Software: The software has undergone several updates since the OmniTom (K171183) was cleared. The updates were implemented to enhance the user experience and improve clinical workflow while using the CT system by adding features based on feedback from our current customers. The updated changes do not impact software. The OmniTom Elite software functions in a similar to manner to the predicate OmniTom (K171183) device.

The internal verification and validation activities and external testing of product safety and EMC / EMI was completed successfully. The differences noted above raise no new issues of safety or effectiveness based on all testing performed. Below a summary has been provided for the testing conducted.

Attributes	OmniTom Elite (subject device)	OmniTom (predicate device – K171183)
Indications for Use	The OmniTom Elite CT system is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 40 cm aperture, primarily head and neck. The CT system is intended to be used for both pediatric and adult imaging and as such has preset dose settings based upon weight and age. The CT images can be obtained either with or without contrast.	The NL5000 [OmniTom] system is intended to be used for x-ray computed tomography applications for anatomy that can be imaged in the 40 cm aperture, primarily head and neck. The CT system is intended to be used for both pediatric and adult imaging and as such has preset dose settings based upon weight and age. The CT images can be obtained either with or without contrast.
Aperture (cm)	40	40
Image Field Of View (cm)	30	30
Detector Material	Gadolinium Oxysulfide	Gadolinium Oxysulfide
Detector Coverage (mm)	16 x 0.625 mm	16 x 0.625 mm
Slice Configurations	16	16
Spatial Resolution MTF at 0% (lp/cm)	Soft tissue kernel: 6.7 lp/cm High resolution kernel: 14.8 lp/cm	Soft tissue kernel: 6.0 lp/cm High resolution kernel: 14.0 lp/cm
X-ray Tube Type	Grounded/Fixed Anode/Monoblock	Grounded/Fixed Anode/Monoblock

Attributes	OmniTom Elite (subject device)	OmniTom (predicate device – K171183)
Heat Storage (MHU)	0.72	0.72
Cooling	Water-Glycol	Water-Glycol
Tube Current (Ma)	5 – 45	5 – 45
Tube Voltage Range (Kv)	80, 100, 120	80, 100, 120
Rotation time (s)	1, 2	1, 2
Gantry Weight (lbs)	1700	1700
Mobile / Stationary	Mobile	Mobile
Battery / Wall power	Lithium Iron Phosphate	Lithium Iron Phosphate
Input Voltage	Single Phase 90 – 264 VAC/1300 watts peak	Single Phase 90 – 264 VAC/1300 watts peak
Max Input Power (Kva)	5.4 Kw	5.4 Kw
PACS DICOM 3.1	Yes	Yes
2D Scout Scan	Yes	Yes
Bolus Tracking	Yes	No
Axial Scan	Yes	Yes
Helical Scan	Yes	Yes
Dynamic Scan	Yes	Yes
2D Viewing	Yes	Yes
MPR Viewing	Yes	Yes

Attributes	OmniTom Elite (subject device)	OmniTom (predicate device – K171183)
3D Viewing	Yes	Yes
Max Scan Range (cm)	40	40
Scan Localizer	Laser	Laser
Cardiac/Respiratory Gating	No	No
Patient Table	No	No
Image recon speed max (images per second)	16 image/s	16 image/s
X-ray Warning Lights	Yes	Yes
110% X-ray Timer	Yes	Yes
Emergency Stop	Yes	Yes
Operator X-ray On Switch	Yes	Yes
Quality Test Phantom	Yes	Yes
Quality Test Report	Yes	Yes
X-ray Filter	Bowtie	Bowtie
Administrator Privileges	Yes	Yes
Dose Display	Yes	Yes
Dose Report / Audit	Yes	Yes
Protocol Override Protection	Yes	Yes
Dose Check	Yes	Yes

Attributes	OmniTom Elite (subject device)	OmniTom (predicate device – K171183)
Pediatric Protocols	Yes By Age/weight	Yes By Age/weight
Automatic Exposure Control	Yes	Yes
Biocompatibility	Yes	N/A
Sterility	N/A	N/A
Chemical Safety	N/A	N/A
EM Emissions	ETL Testing	ETL Testing
Electrical Safety (IEC 60601-1)	ETL Testing	ETL Testing
Mechanical Safety (IEC 60601-1)	ETL Testing	ETL Testing
Where Used	(Mobile) Radiology, ICU, ED, OR, Clinic, Office, Ambulance	(Mobile) Radiology, ICU, ED, OR, Clinic, Office

General Safety and Effectiveness Concerns:
All components of the subject OmniTom Elite CT system that are subject to Federal Diagnostic Equipment Performance Standard and applicable regulations of 21 CFR §1020.30 and §1020.33 are certified to meet those requirements. To minimize electrical, mechanical and radiation hazards, NeuroLogica adheres to recognized and established industry practices.

OmniTom Elite CT system is designed and manufactured to comply with the FDA Quality System Regulations and ISO 13485:2016 requirements. The device is in conformance with all applicable parts of the following FDA recognized consensus standards:

FDA Recognition Number	Standard	Description	Version
19-4	AAMI / ANSI ES 60601-1	Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance	2012
19-8	IEC 60601-1-2	Medical electrical equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility. Requirements and Tests	2014
12-269	IEC 60601-1-3	Medical Electrical Equipment - Part 1-3: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Radiation Protection In Diagnostic X-Ray Equipment	2013
5-89	IEC 60601-1-6	Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability	2013
12-302	IEC 60601-2-44	Medical Electrical Equipment- Part 2-44: Particular Requirements for Basic Safety and Essential Performance of X-Ray Equipment for Computed Tomography	2016
12-273	IEC 60825-1	Safety Of Laser Products - Part 1: Equipment Classification, And Requirements	2007
5-40	ISO 14971	Medical Devices - Application Of Risk Management To Medical Devices	2007

FDA Recognition Number	Standard	Description	Version
13-79	IEC 62304	Medical Device Software - Software Life Cycle Processes	2015
5-117	AAMI / ANSI / ISO 15223-1	Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements	2016
2-258	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2018
2-245	10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	2009
2-174	10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2010
12-325	NEMA XR 25	Computed Tomography Dose Check	2019
NR	NEMA XR 26	Access Controls for Computer Tomography: Identification, Interlocks, and Logs	2012

FDA Recognition Number	Standard	Description	Version
12-330	NEMA XR 28	Supplemental Requirements for User Information and System Function Related to Dose in CT	2018
NR	NEMA XR 29	Standard Attributes on Computed Tomography (CT) Equipment Related to Dose Optimization and Management	2013
12-300	NEMA PS 3.1 - 3.20	Digital Imaging and Communications in Medicine (DICOM) Set	2016
21 CFR subchapter J § 1020.30	FDA	Performance Standards for Ionizing Radiation Emitting Products: Diagnostic x-ray systems and their major components	2019
21 CFR subchapter J § 1020.33	FDA	Performance Standards for Ionizing Radiation Emitting Products: Computed tomography (CT) equipment	2019

The OmniTom Elite was designed and manufactured in accordance with the following FDA Guidance Documents:

- Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2018
- Off-The-Shelf Software Use in Medical Devices, September 2019
- Guidance for Medical X-Ray Imaging Devices Conformance with IEC Standards, May 2019
- Guidance for Industry and FDA Staff: Pediatric Information for X-ray Imaging Device Premarket Notifications, November 2017
- Guidance for Industry and FDA Staff : Laser Products - Conformance with IEC 60825-1 and IEC 60601-2-22, June 24, 2007

- Radiofrequency Wireless Technology in Medical Devices, August 14, 2013

In addition to conformance to the above harmonized standards, OmniTom Elite quality assurance activities include the following:

- Risk analysis and mitigation
- Software verification and validation testing
- System verification and validation testing
- Image quality tests
- Testing at unit level

The software contained in the proposed device has been developed & tested in accordance with IEC 62304, and the FDA guidance for *Content of Premarket Submissions for Software Contained in Medical Devices*. Software is critical to the operation of the OmniTom Elite CT system and a malfunction or design flaw in the software could result in delay in delivery of appropriate medical care. As such, the risk management analysis identified potential hazards which were controlled and mitigated during development of OmniTom Elite. The verification/validation testing ensured the safety and effectiveness of OmniTom Elite.

The OmniTom Elite underwent Electrical Safety and Electromagnetic Compatibility testing and proved to be in compliance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-44.

Design verification and design validation testing was performed to confirm all design and user requirements were met. The proposed OmniTom Elite device demonstrated that the new features did not exhibit any negative effects on the requirements in place, as well as they did not exhibit any concerns that may impact safety and effectiveness.

Software verification and software validation testing was executed to confirm all software requirements were met. The proposed OmniTom Elite device was shown to meet all requirements and to not have any impact on imaging.

Image quality metrics such as noise, slice thickness, low and high contrast resolution, radiation metrics, and modulation transfer function were measured utilizing phantom image quality tests in accordance with the equipment performance standards for diagnostic x-ray systems administered by the FDA. The OmniTom Elite system successfully demonstrated that it has comparable image quality as the predicate device OmniTom (K171183) and meets all the image quality criteria that are used for testing the OmniTom.

Clinical performance of the CT system was evaluated using an ACR Phantom was used to measure image metrics, such as CT number linearity, image slice thickness, image noise,

low contrast resolution and high contrast resolution. The data provided clinical demonstration of the operation of the device and the images reviewed by a board-certified radiologist were of diagnostic quality.

Conclusion

Both the proposed device (OmniTom Elite) and the predicate device (OmniTom) are CT systems that are used for pediatric and adult imaging (same intended use). The overall design of the CT system and basic functionality that it provides to the end user are the same. The differences in technological characteristics do not raise different questions of safety and effectiveness. The results of the performance testing and conformance to the harmonized standards demonstrate that the subject device operates in accordance with specifications and meets user needs and intended use. The OmniTom Elite CT system performs as well in its intended use as similar CT devices currently on the market.